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Clinical Study to Evaluate the Efficacy of *Drakshadi Yog* in the Management of Respiratory Allergic Disorders of Children

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Abstract

Introduction: Children with RADs experience a lot of problems in their day to day activities. Respiratory Allergies pose the greatest stress on the children in most of the developed and developing countries. In India 15-20% population is suffering from RADs. There is no cure for RADs as per the Conventional Medical Science. Ayurvedic medicines can be a potential and effective alternative for the treatment against the RADs. **Materials and methods:** Double blind randomised controlled trial was conducted on 100 patients of RADand were given *Drakshadi Yog*for 12 weeks. **Results:** In intergroup comparison extremely significant gain was seen in trial group (group A) over control group (group B) for nasal discharge, sneezing, nasal obstruction, itching of nose and eye, wheezing and inflammation of throat. Whereas for loss of smell, headache and cough very significant advantage was observed in trial group (group A) over group B. Significant gain was seen in trial group (group A) over control group (group B) for hoarseness of voice. Insignificant gain was found in trial group (group A) over control group (group B), for fever and dyspnea. **Discussion:** No adverse effect was observed. Thus, *Drakshadi Yog* can be recommended for the management of Respiratory Allergic Disorders of Children.

Keywords: *Drakshadi Yog, RAD,*sneezing

Introduction

Children with RADs experience a lot of problems in their day to day activities. Respiratory Allergies pose the greatest stress on the children in most of the developed and developing countries. Respiratory allergic disease are showing upward trend worldwide. In India 15-20% population is suffering from RADs[1].Children with Respiratory Allergic Disorders experience frustration, anxiety and physical, social and emotional disturbances that affect their learning ability. The disorder contributes to headaches, fatigue, limits daily activities, interferes with sleep and leads to school absenteeism. There is no cure for RADs as per the Conventional Medical Science. Ayurvedic medicines can be a potential and effective alternative for the treatment against the RADS. Ayurvedic medicines are used for the treatment of allergic diseases globally so that people all over the world can keep faith on it on the basis of scientific evidences.

Aims and objectives

1. To assess the efficacy of "***DRAKSHADI YOG***" on Respiratory allergic disorders.
2. To provide the relief or improve previous symptoms.
3. To restore normal airway function and to promote healthy life style.

Material and methods

Selection of patients:

Total 100Cases were selected clinically from O.P.D. & I.P.D. of PostGraduate Department of *Balroga* N.I.A. Jaipur (Rajasthan) on the basis of inclusion and exclusion criteria after taking written informed consent.

Criteria for Inclusion:

- Age group 5 to 15 years of either sex.
- Cardinal features of respiratory allergy (Based on allergy, Asthma immunol. 2004)
- History of at least 3 episodes in last one year.
- Past History of recurrent bronchiolitis & recurrent pneumonia in early childhood.

Criteria for Exclusion:

- Severe and complicated respiratory allergic disorders
- Pneumonia
- Tuberculosis
- Plural effusion
- Emphysema
- Lung abscess
- Bronchiectasis
- Pleurisy
- Nasal polyposis
- Congenital anomalies
- Chronic debilitating diseases

Criteria for withdrawal:

The participant may be withdrawn from the trial if there is:

1. Parents/guardian not willing to continue treatment.
2. Appearance of features of respiratory infections.
3. Any other acute illness
4. Patient develops life threatening complication during treatment.

Administration of drug:

Selected patients were given Trial drug and placebo1ml/kg/day in 2-3 divided doses for 12 weeks.Follow up was done every 15 days during the trial and at the end of the treatment.

Assessment criteria:

For assessment of the efficacy of the trial therapy, following parameters were adopted-

1. Clinical Assessment

a) Subjective parameters with grading (scoring) of clinical features

Clinical Assessment: was based on clinical features of respiratory allergic disorders according to both modern and Ayurvedic parameters. Clinical assessment was done on the basis of presenting features on four point scale.

Clinical Assessment Criteria	
Rhinorrhea *(Nasa Srava)*	
• No *Nasa Srava*	0
• *Nasa Srava* only in morning	1
• *Nasa Srava* both in the morning and evening	2
• Continuous *Nasa Srava*	3
Impaired smell (*Gandhagyan*)	
• Normal smell perception	0
• Perceiving smell with difficulty	1
• Perceiving only pungent smell	2
• No smell perception	3
Sneezing (*Kshwathu*)	
• No sneezing	0
• Sneezing when suffering from severe state of disease	1
• Sneezing with mild reasons	2
• Always sneezing	3
Nasal Obstruction *(Ghranoparodha)*	
• No obstruction	0
• Obstruction only during sleep	1
• Intermittent obstruction throughout the day	2
• Complete obstruction throughout the day	3
Headache (*Shirahshoola*)	
• No headache	0
• Occasional headache only at the time of *Pratishyaya*	1
• Frequent headache but not severe	2
• Severe constant headache	3
Hoarseness of voice (*Swarasada*)	
• No hoarseness of voice	0
• Hoarseness of voice at the time of *Pratishyaya*	1
• Hoarseness of voice present but no difficulty in speech	2
• Difficulty to make sound (due to hoarseness of voice)	3
Fever (*Jwara*)	
• No fever	0
• Fever only at night	1
• Mild fever throughout the day	2
• Moderate / severe fever throughout the day	3
Dyspnea (*Shwaskashtata*)	
• No dyspnea	0
• Dyspnea on cold exposure	1
• Dyspnea present and pt. is forced to take	2

medicine for relief	
• Dyspnea not relived even with medicines	3
Itching (Nasal / Eye) (*Nasa/Akshikandu*)	
• No itching	0
• Occasional itching	1
• Itching only at nose	2
• Itching at nose and eyes	3
Wheezing *(Sashabdaswaas)*	
• No wheezing	0
• Mild wheezing	1
• Severe wheezing audible on auscultation	2
• Wheezing audible even without stethoscope	3
Cough *(Kasa)*	
• No cough	0
• Occasional cough	1
• Continuous cough with moderate pain	2
• Continuous cough with severe pain	3
Throat Inflammation (*Galashotha*)	
• No sore throat	0
• Sore throat with pain .No difficulty in food intake	1
• Sore throat with pain and difficulty in food intake	2
• Sore throat with pain which interferes with intake of liquids too	3

Objectives

Following laboratory findings were assessed-

a) Peak Expiratory Flow Rate (PEFR)

b) Laboratory parameters

Blood - (T.L.C, D.L.C, HB%, TEC, IgE)

U.S.G. if needed.

Statistical Analysis

Various observations made and results within groups obtained were computed statistically using Wilcoxon matched-pairs signed-ranks test and Mann whitney test and unpaired and paired t testto find out the significance of the values obtained and various conclusions were drawn accordingly.

Observation and results

Total 110 patients were registered for the present study. Out of them 10 patients dropped out and study was completed on 100 patients.

Table No. 01: Showing statistical Presentation of all the Morbidity features after Treatment in Group A and Group B

S. N.	Morbidity features	Gr ou p	Mean Score			Gain %	S.D.	S.E.	p	Ipt
			B.T	A.T	Diff					
1.	Nasal Discharge	A	1.62	0.68	0.94	58.02	0.46	0.06	<0.0001	ES
		B	1.58	1.48	0.10	06.32	0.30	0.04	0.0625	IS
2.	Loss of Smell	A	1.50	0.76	0.74	09.33	0.52	0.07	<0.0001	ES
		B	1.36	1.34	0.02	01.47	0.51	0.07	0.6250	IS
3.	Sneezing	A	1.30	0.50	0.80	61.53	0.40	0.05	< 0.0001	ES
		B	1.16	1.10	0.06	05.17	0.23	0.03	0.2500	IS
4.	Nasal obstruction	A	1.38	0.68	0.70	50.72	0.54	0.07	< 0.0001	ES
		B	1.34	1.24	0.10	07.46	0.36	0.05	0.1094	IS
5.	Headache	A	1.38	0.74	0.64	46.37	0.52	0.07	< 0.0001	ES
		B	1.20	1.14	0.06	17.88	0.23	0.03	0.2500	IS
6.	Hoarseness of Voice	A	0.82	0.28	0.54	65.85	0.50	0.07	< 0.0001	ES
		B	0.58	0.54	0.04	06.89	0.19	0.02	0.5000	IS
7.	Fever	A	1.18	0.98	0.20	16.94	0.40	0.05	0.0020	VS
		B	1.00	0.94	0.06	06.00	0.23	0.03	0.2500	IS
8.	Dyspnea	A	1.34	1.18	0.16	11.94	0.37	0.05	0.0078	VS
		B	1.14	1.04	0.10	08.77	0.30	0.04	0.0625	IS
9.	Itching(nasal/ eye)	A	1.58	0.94	0.64	40.00	0.48	0.06	< 0.0001	ES
		B	1.60	1.50	0.06	03.75	0.23	0.03	0.2500	IS
10	Wheezing	A	1.22	0.46	0.76	67.85	0.47	0.06	< 0.0001	ES
		B	1.12	1.04	0.08	07.14	0.27	0.03	0.1250	IS
11	Cough	A	1.46	0.78	0.68	46.57	0.51	0.07	< 0.0001	ES
		B	1.36	1.28	0.08	05.88	0.27	0.03	0.1250	IS
12	Throat inflammation	A	1.38	0.58	0.80	57.97	0.60	0.08	< 0.0001	ES
		B	1.14	1.08	0.06	05.26	0.23	0.03	0.2500	IS

Statistical evaluations of overall morbidity features showed good result in group A patient, treated with Syrup *Drakshadi Yog* I. In nasal discharge, loss of smell, sneezing, nasal obstruction, headache, hoarseness of voice, itching of nose and eyes, wheezing, cough and inflammation of throat extremely significant improvement ($P<0.0001$) was seen in group A. Where as in other features such as fever and dyspnea very significant improvement ($P<0.001$) was seen in group A.On the other hand, in group B all the outcomes were insignificant.

Objective parameter

Table No.02: Showing statistical Presentation of Intergroup comparison of lab investigations

Sr. No	Morbidity features	Groups	Mean	S.D.	S.E.	t	p	Ipt
1.	Hb%	A	0.5960	0.7556	0.1069	2.275	0.0251	S
		B	0.3160	0.4316	0.0610			
2.	TLC	A	1062.0	1805.1	255.28	1.768	0.0801	NS
		B	602.00	353.11	49.938			
3.	Neutrophils	A	12.280	8.985	1.271	1.597	0.1135	NS
		B	9.780	6.466	0.9144			
4.	Lymphocyte s	A	35.940	10.991	1.554	2.436	0.0166	S
		B	30.320	12.052	1.704			
5.	Eosinophil Count	A	4.100	3.272	0.4627	8.512	< 0.0001	ES
		B	0.1000	0.5803	0.0820			
6.	TEC	A	233.66	163.71	23.152	10.066	< 0.0001	ES
		B	0.5800	2.914	0.4122			
7.	IgE	A	74.240	45.235	6.397	11.558	< 0.0001	ES
		B	0.2600	1.468	0.2076			

In intergroup comparison between group A and group B of lab investigations, extremely significant change at the level of (P<0.0001) for Eosinophil count, TEC and IgE wasobserved.Whereas for Hb% and Lymphocyte countsignificant (P<0.01) advantage was observed in group A over group B.Insignificant (P>0.05) gain was found in group A over B, for TLC and Neutrophil count.

Discussion

The compound drug "*Drakshadi Yog* I" is the combination of drugs having *Amapachaka* (e.g *Haritiki* and *Pippali*), *Rasayana* (e.g. *Haritiki* and *Pippali*), *Sothahara* (eg.*Yavasa, Haritiki* and *Pippali*) and *Shleshmahara (*e.g *Draksha, Yavasa, Haritiki* and *Pippali*) *Jwarahara* (e.g *Draksha, Yavasa, Haritiki* and *Pippali*) and S*hulahara* (e.g *Pippali*), *Vedana-sthapana (*e.g *Yavasa and Haritiki), Sothahara (*e.g *Yavasa, Haritiki)* properties.

These drugs were selected on the guidelines given by Acharya, easy availability at low cost & research works conducted regarding these drugs in various research institutes. The various published data on the anti inflammatory, anti allergic, immuno modulatory and anti-asthmatic actions of the individual drugs as referred in the drug review in this work substantiates the classical profiles of the drugs as described in Ayurvedic classics.

The Study drug is having *Katu, Tikta, Kashaya* and *Madhura Rasa*, *Laghu*, *Sara,Ushna* and *TeekshnaGuna* and *MadhuraVipaka,Ushna Virya* and *Kapha Vata Shamaka* properties. It shows *Srotoshodaka* properties which may possibly assist to eliminate sluggish *Dosha* in the *Srotas*.

Katu, Tikta and *Kashaya Rasa, UshnaVirya* and *Laghu, Ushna, TeekshnaGuna* having the properties of *Kapha-Vilayana, Pachana, Srotoshodaka*. Due to this liquification of

KaphaDosha takes place resulting in clearing of respiratory tract on coughing. *SaraGuna* having the quality of *Vatanulomna.*

Most of the drugs have *Vata KaphaShamaka* properties. *Drakshadi Yog I* is having a potential properties of alleviating both *Vata* and *KaphaDosha* by virtue of *Tikta, Katu, KashayaRasa* and *UshnaVirya*, *Laghu,Sara, Teekshna* and *Ushna* properties. Thus, *KaphaShamaka* properties of drug help in breaking the *Srothorodha* and digestion of *Ama*, which leads to proper functioning of the *Agni*.

Draksha having the property of *Vatanuloman* due to *Sara Guna, Vatashamaka* property due to *Madhura Rasa, Snigdha Guna* and *MadhuraVipaka, Kaphashamaka* property due to *Kashaya Anurasa*. *Yavasa* having the property of *Vatashamaka* due to*Madhura* and *Tikta Rasa, Kaphashamaka property* due to *Laghu Guna* and *Tikta Rasa Vatanuloman* property due to *Sara Guna*. *Abhaya* having the property of *Kaphashamaka* due *to Kashaya-Katu-Tikta Rasa, Laghu and Ruksha Guna,Vatashamaka* property due to *Madhura Vipaka* and *Vatanuloman* property due to *Ushna Virya* and *Deepan-Pachan* property due to *Katu Rasa. Pippali* having the property of *Vatanulomana* and *Shulaprashamana* due to *Snigdha-Ushna Guna, Kaphashamaka* property due to *Katu Rasa* and *Laghu-Tikshana Guna, Vatashamaka* property due to *Madhura Vipaka* and *Snigdha Guna, Deepan-Pachan* property due to Katu Rasa and *Rasayana* property due to *Madhura Vipaka*.

Some ingredients of the study drug having *Rasayana* (immunomodulator) quality, which helps to improve *Dhathu* both qualitatively and quantitatively. (e.g *Terminelia chebula* and*Piper longum,). Haritiki* and *Pippali* are very good *Rasayan* for *Pranvahasrotas* which is main site of manifestation of RAD.

The components of the study drug might have acted at various levels in breaking the pathogenesis of the allergic disorders. Some hampers the immediate hypersensitivity reaction by inhibiting histamine release, or by inhibiting mast cell degranulation as for e.g. *Vitis vinifera* and*Piperlongum* depletes histamine from bronchial and lung tissues.Mast cell inhibitory activity is possessed by *Terminelia chebula* and *Piperlongum*.On the other hand some are effective for late phase allergy owing to the inhibitory action on leukotrine systems as or by reducing the eosinophil count. e.g. *Vitis vinifera* and*Piperlongum.*

The efficacy of trial drug in reducing the nasal discharge is because of the *Vata* and *Kapha Shamaka* qualityof the drug. The anti-allergic, anti-inflamatory and *Rasayana* (immunomodulator) effect of various ingredients is responsible for the overall relief in the symptoms, including nasal discharge, sneezing, itching etc. (e.g. *Draksha, Yavasa, Haritiki* and *Pippali).*

Cough in RAD is mainly due to post-nasal dripping causing throat irritation. Improvement in cough may be because of pacification of *Vata* and *KaphaDosha* and removal of obstructing *Kapha* from the *Pranavaha Srotas* due to anti-tussive and mucolytic properties of the ingredients as *Pippali.*Expectorant action was also attributed to *Yavasa* because of flavonoids, tannins, sterols, triterpene, saponins and anthroquinones alkaloids.

Relief from dyspnea and reduction in wheezing was because of relieving the obstruction in passage of *Pranavayu* by *Samakapha*. The probable action of drug was because of its *KaphaVatahara* effect and *Ushna, TeeksnaGuna*. The relief might be the result of bronchodilator action of *Pippali.*[2] Spasmolytic action of *Pippali* acts by inhibiting the contractile action of histamine by glycoside saponin. *Terminelia chebula* has potent mast cell stabilizing

property also has anti histaminic effect by Ellagic acid Tannins Chebulagic acid.

Nasal obstruction, throat inflammation, loss of smell and hoarseness of voice are because of edematous and later on inflammatory changes in various target organs in the disease process. The study drug showed significant anti-inflammatory effect. (e.g. *Draksha, Yavasa* and *Pippali*.

Headache is mainly because of allergic sinusitis accompanying the RADs. Significant relief from headache after treatment was observed which might be due to anti-inflammatory properties of *Draksha, Yavasa* and *Pippali*. In addition, *Vata Dosha* get pacified and becomes responsible for the relief. *Pippali*also proved to possess analgesic property.

Mild inflammation due to allergic reaction showed marked relief. It may be because of proven anti-inflammatory activity of *Draksha, Yavasa* and *Pippali*.

Increased Hb % after treatment is suggestive of the effect of trial drug in improving *RasaDhatwagni* owing to the effect of *Haritiki,Pippali* and thereby the quality of *RaktaDhatu*. In addition, the drug has *Amapachaka* and *Srotoshodhaka* effect. Thus, by cleansing the channels and by increasing the absorption, it has improved the appetite and digestive power of the patients.

Improvement in the status of leucocyte count shows the anti-inflammatory activity of trial drug. It may be attributed to immunomodulatory and its anti-inflammatory effect of various components such as *Draksha, Yavasa* and *Pippali*.

Eosinophils are key effector cells of inflammatory response in RAD. Reduction in eosinophil and IgE is suggestive of potent anti-allergic and anti-inflammatory activity of the study drug such as *Draksha, Yavasa* and *Pippali.*

Increased PEFR is suggestive of the fact that, trial drug could have modified the existing airflow limitation caused due to obstruction. *Haritiki* and *Pippali* have *Deepana, Pachana* and *Amadosh hara* properties. Thereby, the drug is helpful in restoring normal breathing. As *Pippali* and *Haritiki* act as *Rasayan* on *Pranvahasrotas*, it may have worked on quantitative and qualitative improvement of lung structure and function.

The insignificant change in the condition of patient after follow up with respect to after treatment position is suggestive of requirement of long-term therapy.

From this research work, it has been concluded that along with anti-allergic & bronchodilator effect, immunomodulatory regimen will play a key role in future therapies for allergic respiratory diseases. These treatment modalities may not only treat allergic disease, but also be beneficial in reducing the morbidity and mortality for which it is responsible.

Psychological stress may be an additional environmental factor that worsens the oxidative toxicity[3] the ingredients like, *Pippali* by their anti-stress activity are responsible for regression of symptoms.

Thus, overall improvement in the condition of the patient of the study group may be because of the multidimensional properties of the drug. (*Vatakaphahara, Deepana, Pachana*, and *Vatanulomana* properties), which are essential for breaking down pathogenesis of RAD. The main factor in this disease as in many other diseases is *Ama*, and the *Deepana*–*Pachana* properties of the drug will digest the *Ama* by improving the *Jatharagni* as well as *Rasagni and Bhutagni*. Furthermore, the *Sothahara Karma* of most of the contents will neutralize the *Srotorodha* in *Pranavaha Srotasa* due to *Sotha* created by *Sama Vata*.

Conclusion

11-15 years age group was the most affected group. Males were more susceptible to RADs as compared to females. Maximum numbers of cases were belonging to urban

area and middle socio-economic status. Maximum number of cases exhibited seasonal manifestation. Hereditary influence is evident in RADs.The provocating factors observed were dust, smoke, seasonal changes, cold air, cold water, cloudy weather physical stress, spicy and oily food, sour food items and mental stress. Associated complaints found are snoring, serous otitis media, tonsillitis and migraine. The characteristic behavior and appearance were observed in the form of allergic shinners, nasal crease, allergic cluck, allergic salute and allergic gape. *Kapha Vata Prakriti* patients were found to be more susceptible for RADs. Maximum number of patients of the trial was under *Mandagni*. IgE level was found to be elevated in 86.00% and 90.00% in group A and B respectively. TEC level was found to be elevated in 90.00% and 88.00% in group A and B respectively. After treatment follow up study showed that research drug provides the long-term sustained relief. No adverse effect, of the study drug was observed during the study.

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